proteus
DIGITAL HEALTH

March 15, 2019

VIA ELECTRONIC FILING
Ms. Marlene H. Dortch
Secretary
Federal Communications Commission
445 12th Street, S.W.
Washington, D.C. 20554

Re: Ex Parte Notice: Promoting Telehealth for Low-Income Consumers – WC Docket No. 18-213

Dear Ms. Dortch:

This letter is submitted, pursuant to Section 1.1206(b)(1) of the FCC's rules, to notify you that representatives of Proteus Digital Health®, Inc. ("Proteus"), had separate meetings on March 14, 2019 with Commissioner Brendan Carr and Evan Swarztrauber, Policy Advisor to Commissioner Carr; Travis Litman, Chief of Staff and Senior Legal Advisor, Wireline and Public Safety, for Commissioner Jessica Rosenworcel; and Karen Onyeije, Ben Bartolome, Dr. Chris Gibbons and Dr. David Ahern of the FCC's Connect2Health Task Force. Attending the meetings on behalf of Proteus were the undersigned and Bryan Tramont of Wilkinson Barker Knauer, LLP.

Proteus's representatives highlighted the company's work in "digital medicines" and its implications for patient well-being and reducing healthcare costs. They noted that digital medicines enable monitoring of medication-taking patterns and thereby allow a healthcare provider or caregiver to determine whether a patient is following his or her medication regimen. Proteus's representatives also explained the mechanics of how digital medicines work and how they permit healthcare providers to monitor medication intake remotely; discussed the other relevant biometric data collected via digital medicine technology; noted the high success rates Proteus has achieved in clinical trials; and identified specific medical conditions where digital medicines can be especially effective.

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In addition, Proteus's representatives emphasized how digital medicines can achieve the objectives of the Connected Care pilot program described in the Notice of Inquiry for the above-referenced proceeding. They recommended that the Commission take particular note of pilot proposals that include digital medicines in their "toolbox" of telehealth applications. Acknowledgement of the value of digital medicines would be consistent with the program's focus on delivering broadband-enabled telehealth services and applications to low-income patients and veterans outside of brick-and-mortar health care facilities, while achieving the program's fundamental objective of improving patient outcomes. Lastly, Proteus's representatives left behind the attachment to this letter.

Please contact the undersigned if you have any questions.

Very truly yours,

/s/ Bruce Carroll

Bruce M. Carroll Jr.
Vice President, Healthcare Policy & Market Access

cc: Commissioner Brendan Carr
Evan Swarztrauber
Travis Litman
Karen Onyeije
Ben Bartolome
Dr. Chris Gibbons
Dr. David Ahern

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Digital Medicines – a New Kind of Pharmaceutical

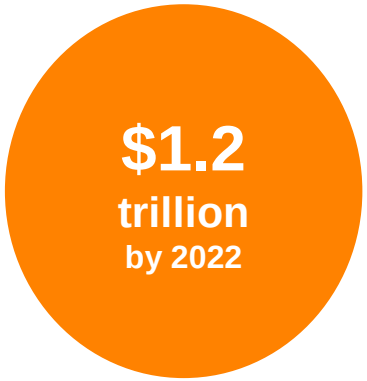
Proteus Digital Health, Inc.
Bruce M. Carroll Jr., Vice President, Healthcare Policy & Market Access
WT Docket No. 18-213 – Connected Care Notice of Inquiry
March 14, 2019

Some Facts About Proteus

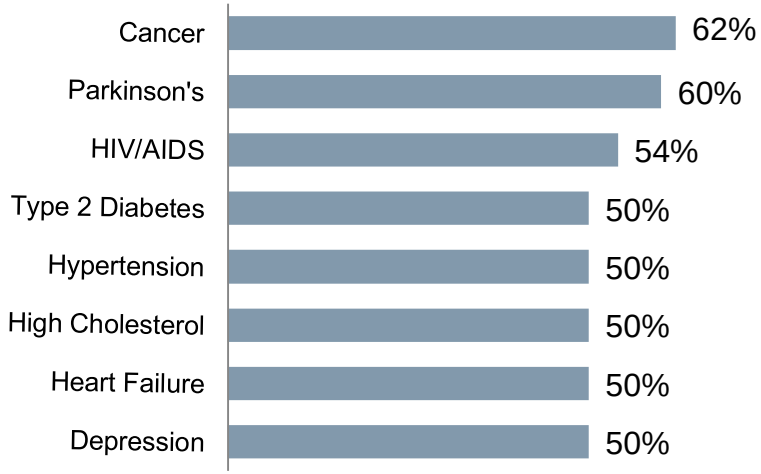
- World's first digital medicines company
- Vision: harness digital technologies to make medicines safer and more effective
- Headquartered in Redwood City, CA
- Privately held
- Founded in 2001
- Approximately 300 employees
- Holder of over 500 patents, plus regulatory clearances in the U.S., European Union and China

The Challenge: Patients Often Do Not Take Their Medications

Global Pharmaceuticals

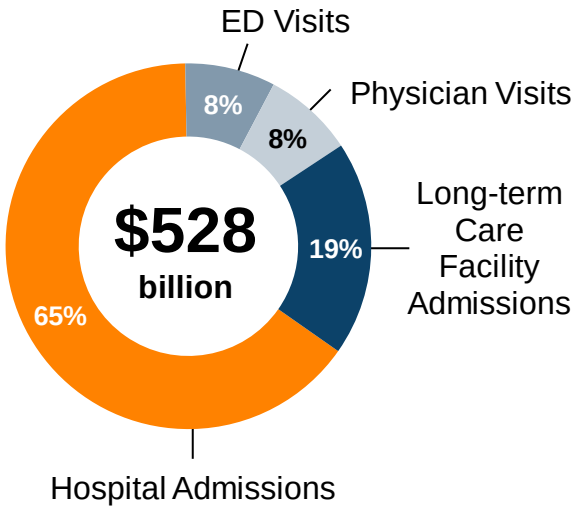


Consumers Don't Take Their Drugs



Medication Possession Ratios (MPR)
Actual adherence likely 25% to 35%

Cost of Medication Non-Adherence at Least $500B Annually in U.S.



Sources: Chronic conditions: making the case for ongoing care (Johns Hopkins University); Comparison of Drug Adherence Rates Among Patients with Seven Different Medical Conditions (Pharmacotherapy); Patient Adherence: The Next Frontier in Patient Care; Annals of Internal Medicine ; Nonadherence to antihypertensive drugs (American Heart Association); Nonadherence to antihypertensive drugs (Abegaz et al. Medicine 96:4)

Proteus's Solution: Ingestible Sensors

The world's smallest, safest, global regulator-approved medical device.

Proteus Ingestible Sensor

Silicon: 0.9mg
Bananas: 5mg
per 100 grams

Copper: 0.02mg
Cashews: 2.2mg
per 100 grams

Magnesium: 0.01mg
Halibut: 107mg
per 100 grams

- Cleared by FDA, CFDA, CE Marked in Europe
- Designed to be incorporated into medicines
- Supported by technology and data platforms

Inside Digital Medicines, or “DigiMeds™”

Medications with Proteus sensors

The sensor is placed inside a small pill.

Prescribed medication

The sensor contains tiny amounts of silicon, copper and magnesium that pass through the body naturally, just like the fiber in food.

On order of a physician, a pharmacist puts a Proteus sensor inside a capsule, along with each dose of a patient’s prescribed medication.

How DigiMeds Work

Used by Providers

Used by Patients

Digital Drugs

The sensor sends a signal to the patch as it passes through the stomach.

Wearable Sensor

The patch detects and records the date and time of drug ingestion, and sends this info to the app along with records of steps, activity rest, and heart rate.

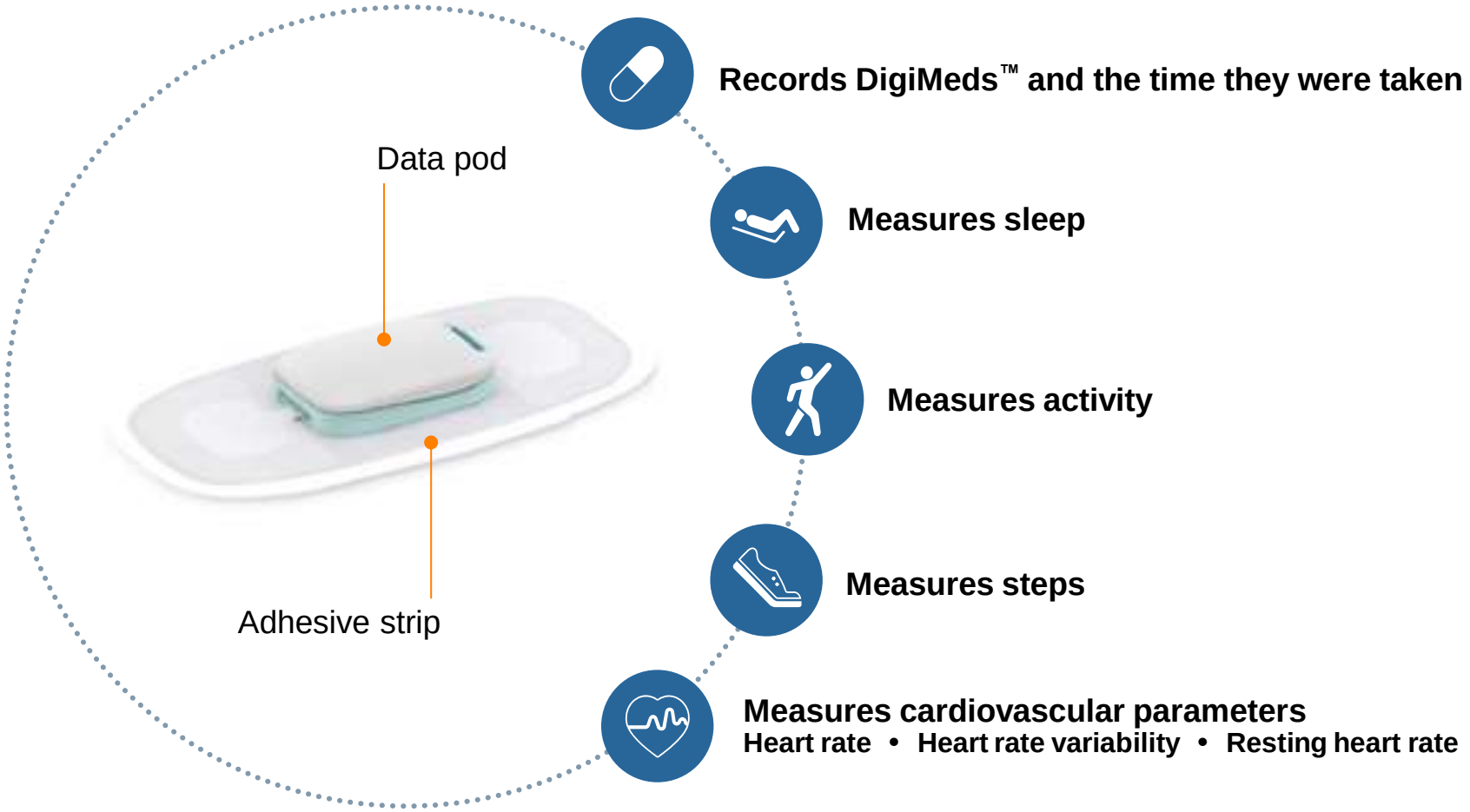
Mobile App

The app allows patients to see how they are doing and share with their healthcare team via an Internet portal.

Healthcare Provider Web/Mobile/EHR App

Links Drug Taking Behavior to Physiologic Response

Beyond DigiMeds,™ the Proteus Patch automatically captures relevant biometric data

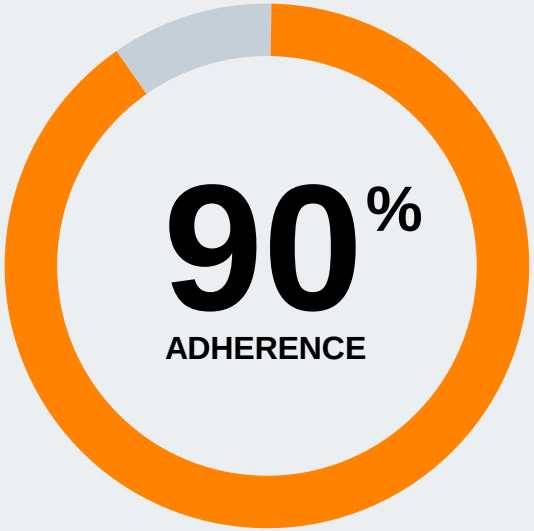


Advantages of DigiMeds

- Patient receives regular feedback about his or her medication-taking behaviors
- Allows a healthcare provider or caregiver to determine whether a patient is following his or her medication regimen
- For the healthcare team, digital medicines improve patient outcomes by measuring ingestions and providing data that leads to improved clinical decision-making and patient engagement
- Reduces or eliminates office visits or hospital stays due to failure to take medications as prescribed
- Because healthcare providers may monitor a patient's medication intake remotely, patients may consult with their physicians on medication issues without having to travel
- Digital medicines can be especially useful for treating chronic conditions (e.g. hypertension, as well as post-traumatic stress disorder and other mental health conditions, where incorrect use of medication can lead to hospitalization.

Clinical Studies Demonstrate the Benefits of DigiMeds

Non-adherence to medicines is a universal problem with a universal solution



Utilizing Proteus DigiMeds™ platform in numerous clinical studies covering chronic therapeutic areas.

97% detection rate

120 + clinical studies

2,600 + subjects

170,000 + sensor ingestions

88,000 + days of patch use

37% reduction in ER visits

98% at goal

89% find it user friendly

86% more motivated

95% say it's easy to use

Digital Medicines Can Achieve the Objectives of the Connected Care Pilot Program

- Takes monitoring of medication intake beyond “brick and mortar” healthcare facilities
- Improved patient outcomes and lower costs for low-income patients and veterans
- As low-income Americans become increasingly reliant on smartphones to access the Internet, Proteus’ mobile-friendly technology will provide them with a readily-accessible healthcare tool
- Benefits of DigiMeds can be measured and quantified

Recommendations

- Proteus asks the Commission to take particular note of pilot proposals that include digital medicines in their “toolbox” of telehealth applications. As the Commission conducts policy in this arena, it should be willing to consider all telehealth innovations in the marketplace (including digital medicines), and promote their use.
- Acknowledgement of the value of digital medicines also would be consistent with the program’s focus on delivering broadband-enabled telehealth services and applications to low-income patients and veterans outside of brick-and-mortar health care facilities, while achieving the program’s fundamental objective of improving patient outcomes.
- Proteus also urges the Commission to continue its efforts to promote broadband deployment to unserved and underserved areas, whether through the Connected Care pilot program or otherwise. Identifying and eliminating broadband coverage gaps will help unleash the full potential of telehealth for all Americans.

Contact Information

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